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any covered services for which the enrollee has already paid the MA organization or provider.

[63 FR 35107, June 26, 1998, as amended at 75 FR 19812, Apr. 15, 2010]

EFFECTIVE DATE NOTE: At 68 FR 20349, Apr. 4, 2003, § 422.626 was added. This section contains information collection and record-keeping requirements and will not become effective until approval has been given by the Office of Management and Budget

Subpart N—Medicare Contract Determinations and Appeals

SOURCE: 63 FR 35113, June 26, 1998, unless otherwise noted.

§ 422.641 Contract determinations.

This subpart establishes the procedures for making and reviewing the following contract determinations:

- (a) A determination that an entity is not qualified to enter into a contract with CMS under Part C of title XVIII of the Act.
- (b) A determination to terminate a contract with an MA organization in accordance with § 422.510(a).
- (c) A determination not to authorize a renewal of a contract with an MA organization in accordance with § 422.506(b).

§ 422.644 Notice of contract determination.

- (a) When CMS makes a contract determination, it gives the MA organization written notice.
 - (b) The notice specifies—
- (1) The reasons for the determination; and
- (2) The MA organization's right to request a hearing.
- (c) CMS-initiated terminations—(1) General rule. Except as provided in (c)(2) of this section, CMS mails notice to the MA organization 90 calendar days before the anticipated effective date of the termination.
- (2) Exception. If a contract is terminated in accordance with §422.510(b)(2)(i) of this part, CMS notifies the MA organization of the date that it will terminate the MA organization's contract.
- (d) When CMS determines that it will not authorize a contract renewal, CMS mails the notice to the MA organiza-

tion by August 1 of the current contract year.

[63 FR 35113, June 26, 1998, as amended at 72 FR 68724, Dec. 5, 2007; 75 FR 19813, Apr. 15, 2010]

§ 422.646 Effect of contract determination.

The contract determination is final and binding unless a timely request for a hearing is filed under 422.662.

[72 FR 68724, Dec. 5, 2007]

§ 422.660 Right to a hearing, burden of proof, standard of proof, and standards of review.

- (a) *Right to a hearing*. The following parties are entitled to a hearing:
- (1) A contract applicant that has been determined to be unqualified to enter into a contract with CMS under Part C of Title XVIII of the Act in accordance with § 422.501 and § 422.502.
- (2) An MA organization whose contract has been terminated under § 422.510 of this part.
- (3) An MA organization whose contract has not been renewed under § 422.506 of this part.
- (4) An MA organization who has had an intermediate sanction imposed in accordance with §422.752(a) through (b) of this part.
- (b) Burden of proof, standard of proof, and standards of review at a hearing. (1) During a hearing to review a contract determination as described at §422.641(a) of this subpart, the applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of §422.501 and §422.502 of this part.
- (2) During a hearing to review a contract determination as described at §422.641(b) of this subpart, the MA organization has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of §422.506 of this part.
- (3) During a hearing to review a contract determination as described at §422.641(c) of this subpart, the MA organization has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of §422.510 of this part.